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### **Claim Amendments**

The claims have been amended to specify that the saccharides are conjugated to a carrier protein. Support for this claim amendment is found in the specification, for example, at page 4, line 5.

In addition, claim 1 has been amended to specify a level of O-acetylation at the C-7 position from  $\leq 29\%$  to  $2-9\%$  and a level of O-acetylation at the C-9 position from  $\geq 26\%$  to  $35-55\%$ . Similarly, claim 2 has been amended to specify a level of O-acetylation at the C-7 position from  $\leq 9\%$  to  $2-9\%$  and a level of O-acetylation at the C-9 position from  $\geq 29\%$  or  $\leq 27\%$  to  $35-55\%$ . Claim 27 has been amended to specify a level of O-acetylation at the C-9 position increases to  $35-55\%$ . Support for these amendments is found in the specification, for example, at page 4, lines 5-10.

Corresponding amendments have been made to claims 5, 8, 9, 11 and 26 based on page 4, lines 5-10 and page 5, lines 23-30 of the specification. Dependent claims 3 and 4 have been amended to refer to preferred ranges disclosed at page 4, lines 5-10 of the specification.

Claim 19 has been amended to recite that the serogroup A antigen is a modified saccharide in which one or more of the hydroxyl groups on the native saccharide has/have been replaced by a blocking group. Support for this amendment is found in the specification, for example, at page 17, lines 12-14.

Claims 10, 24 and 26 have been cancelled.

Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. No new matter is added.

### **Reply to Restriction Requirement**

Responsive to the Restriction Requirement, Applicant provisionally elects the claims of Group I (claims 1-12), drawn to acetylated meningococcal capsular

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saccharide conjugates and compositions comprising such, for continued examination, with traverse. The Examiner has asserted that WO03/007985 anticipates claim 1. However, the Examiner has not provided any explanation as to why WO03/007985 anticipates claim 1.

The amended claims are novel over WO03/007985 because the cited reference does not disclose the meningococcal strains that were used in the purification protocol. Different strains of Men-W135 and Men-Y bacteria have different degrees of native O-acetylation, with some strains even being non-O-acetylated ("O-Ac-"). A process is defined by both its starting materials and its process steps and, although the process steps in WO03/007985 and the present examples may be the same, the starting materials in WO03/007985 (i.e., the meningococcal strains) are not disclosed - no strain names, no deposit details, and no mention of their O-acetylation status. In the absence of this detail, the skilled artisan would not conclude that the Men-W135 and Men-Y saccharides of WO03/007985 would have the claimed levels of O-acetylation at their 7- and/or 9- positions.

In contrast to WO03/007985, the present application defines a target to aim at. The skilled artisan is instructed to obtain a Men-W135 or Men-Y saccharide with a specific range of O-acetylation at the 7- and/or 9- position. Therefore, unlike WO03/007985, a skilled artisan aiming to repeat the present disclosure will select an appropriate starting strain (e.g., the OAc+ strains at page 27, line 5 of the specification) and, during purification and conjugation, will select conditions that provide a product within these ranges and/or will retain only fractions that meet these requirements. Thus, unlike WO03/007985, the end product will be reliably and reproducibly within the claimed. Thus, the claims are linked by a novel special technical feature because the art raised by the Examiner does not teach a Men-W135 or Men-Y saccharide with a specific range of O-acetylation at the 7- and/or 9- position. Applicants therefore respectfully request that the Examiner withdraw the lack of unity restriction.

Responsive to the Species Requirement, Applicant elects serogroup W135. Claims 1, 3-8, 11-23, 25 and 27 are readable on the elected species.

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Applicants expressly reserve the right under 35 U.S.C. § 121 to file a divisional application directed to the nonelected subject matter.

Respectfully submitted,

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/Helen Lee/

Dated: **February 10, 2011** By: \_\_\_\_\_

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